**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| NATERA, INC.,<br><br>Plaintiff,<br><br>v.<br><br>ARCHERDX, INC., ARCHERDX, LLC, AND INVITAE CORPORATION<br><br>Defendants. | C.A. No. 20-cv-125-LPS<br>(Consolidated)<br><br>**FILED UNDER SEAL** |

**DEFENDANTS' RESPONSE TO PLAINTIFF'S SEPTEMBER 1, 2021 DISCOVERY DISPUTE LETTER**

Dated: September 3, 2021

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*Attorneys for Defendants*

Dear Judge Stark:

Defendants hereby respond to Natera's September 1 letter (hereinafter, "Letter"). D.I. 307.

## I. RFP No. 9 (Design, Testing, Performance, and Sales of the Accused Products)

### A. Defendants Have Produced All Responsive Documents to RFP 9—And More

Not only have Defendants produced materials responsive to RFP No. 9, Natera has been in possession of most of those materials since November 2020. Defendants have complied with their obligations, and Natera fails to specify what it seeks that Defendants have not yet produced.

In April 2021, the parties agreed that Defendants would provide three categories of information for six customers selected by Natera. D.I. 175.[1] For the second category, Defendants agreed to produce "documents sufficient to show…instructions for use, product protocols, and/or product manuals ***provided to the customer*** including any testing or customization of any of the accused products for the customer and steps or process the customers perform with the accused products." *Id.* at 6 (emphasis added). Despite Natera's protests to the contrary, Defendants produced virtually all of the instructions for use and product protocols by November 2020. Ex. 1 at 6–10.

Natera nonetheless complains there are documents "Defendants have still not produced." Each complaint is without merit. **First**, Natera alleges Defendants have not produced primer sequences. Natera, however, has been in possession of this since November 2020. Defendants have explained this repeatedly by interrogatory response and emails. Ex. 1 at 10-11; Exs. 2–3. Natera questioned Defendants' witness Dr. Ryan Walters about primer sequences at length. Ex. 4. Defendants also produced detailed GTF files that list the genes and the locations of target loci. Exs. 2–3. **Second**, Natera alleges that it does not have the nucleic acid input type for the accused products. Also incorrect. All the product manuals state—prominently in the overview section—the nucleic acid input type. Exs. 5–12. **Third**, Natera alleges it does not have primer melting temperatures. As Defendants have repeatedly informed Natera, at least as early as November 6, 2020, Defendants do not regularly record melting temperature, and do not provide this information to customers. Ex. 13. Where such records did exist, Defendants produced those documents, even though it exceeded the scope of RFP No. 9. Ex. 1 at 10–11; Exs. 14–15. There is no justification for further melting temperature information. Indeed, in view of the Court's claim construction order and the extensive melting temperature provided to date, Natera cannot possibly prove infringement of the one patent for which melting temperature is relevant. *See* D.I. 243 at 10-11. Defendants have explained this repeatedly in meet and confer, and Natera has yet to provide a response. **Fourth**, Natera seeks primer concentration. Defendants have informed Natera that primer concentration information, outside of what is referenced in product manuals that have been

[1] Natera now alleges that Defendants failed to produce responsive documents to RFP No. 9 in contravention of the Court's January 19 order. Defendants, however, initially agreed to produce documents sufficient to detail use in the U.S. in response to RFP No. 9. At a minimum, Defendants interrogatory responses, identifying these documents months before the substantial close of discovery, show that Natera's allegation is baseless. Ex. 1 at 6–10.

in Natera's possession since November 2020, is not provided to customers and falls outside of the scope of RFP No. 9. Ex. 3; *see also* 5–12. Nevertheless, Defendants have provided Natera with internally used primer concentration information. Defendants have not only met their obligations, but far surpassed them.

### B. Natera's "Representative Customer" Demand

Natera also demands that Defendants designate a set of 22 cherry-picked customers as "representative," allegedly because this is needed to prove inducement. Natera's demand, however, is simply so that it can paint a distorted, prejudicial, and abusive picture of Archer's customer base as being loaded with big-ticket pharma companies and/or companies where Natera competes for customers. Natera does not need this prejudicial designation for inducement. To the extent Natera contends it needs to prove inducement, Archer has designated "a set of 24 instructional manuals that are broadly made available to Defendants' customers." Ex. 2. The parties agreed that "this set is fairly representative of the instructional use materials [Defendants] provide to customers for the accused products, such as protocols and product inserts. The set include documents relating to the FusionPlex, LiquidPlex, VariantPlex, and Immunoverse product lines at issue in this case." *Id.* The parties also agreed to the identification of representative technical materials for STARATFIDE and PCM. Ex. 16. This is more than sufficient and reasonable for inducement purposes.

## II. RFP No. 1 (FDA Documents)

Natera received the vast majority of Defendants' regulatory documents in the summer of 2020, in the first productions from Archer. Natera then received a supplemental production of regulatory documents in early 2021. Natera now seeks materials relating to a single FDA meeting that occurred on March 8, 2021. Natera, however, never explains either in its letter or in meet and confer why this one meeting is relevant; when it deposed Defendants' 30(b)(6) witness on FDA communications, it did not even ask about this meeting. In an effort to minimize the dispute, Defendants' have nonetheless produced the relevant meeting minutes. While Defendants voice their ongoing objection to the notion that they must produce every scrap of paper exchanged with the FDA, this issue is moot.

## III. Interrogatory No. 2 / RFP No. 8 (Archer's use of the Accused Products)

Natera asks for the Court to compel the production of documents sufficient to show the number of uses, including those that are related to the pursuit of FDA approval, which are not infringing as a matter of law under the Safe Harbor of 35 U.S.C. § 271(e). While Defendants should not have to produce information for non-actionably uses, to avoid further dispute, Defendants have produced information showing the scope of sales undisputedly excluded from any damages calculations due to the Safe Harbor. As such this issue is moot.

## IV. Natera's 30(b)(6) Deposition Topics

- **Topics 1-2:** Defendants agreed to produce witnesses to testify to the full scope of these two topics regarding R&D of the accused products and AMP, with the exception of testimony regarding the identity of "all persons substantively involved." Ex. 19. It makes

little sense to have a witness list out a series of names or discern what Natera means by "substantively involved." Defendants already provided a list of individuals most knowledgeable on these issues in early 2021. Exs. 17–18.

- **Topic 9:** This request seeks "the circumstances and communications relating to regulatory status of" the accused products. Ex. 19. Defendants agreed to designate a witness—and have provided a witness—on past and current regulatory status. Natera further demands ***future*** or ***contemplated*** filings. Defendants should not have to produce a witness to speculate about the future, particularly since uses of the accused products associated with future FDA applications will not be infringing as a matter of law pursuant to the Safe Harbor.
- **Topic 10:** Natera asserts that it needs a witness on topic 10 regarding "product design for customers." Ex. 19. Defendants, however, have already produced two witnesses to testify about product design pursuant to Topics 1–2. No more witnesses are required.
- **Topics 17, 20-21, 22:** Natera seeks the inventory of the accused products (Topic 17), but has never explained relevance. Ex. 19. The asserted claims are method claims and are not infringed by inventory. Natera also seeks testimony regarding reimbursement rates and insurance coverage (Topics 20-22). *Id.* But no accused products sold in the United States are covered by insurance and as such it makes little sense to require Defendants to provide a witness to discuss non-existent insurance coverage.
- **Topics 45-46:** Natera seeks a witness to testify on Invitae's pre-acquisition valuation of Genosity (Topic 46), but provides no explanation of relevance. Ex. 19. Indeed, there is none. This valuation is not probative to any claim at issue. What's more, Natera has a separate lawsuit against Genosity, so imposing an unrelated discovery inquiry in this case should not be permitted. *See Natera, Inc. v. Genosity Inc.*, C.A. 20-cv-1352 (D. Del.). Natera has also provided no explanation of relevance for its pursuit of Invitae's pre-acquisition valuation of Archer (Topic 45). As above, such testimony would not relate to damages. Defendants provided Natera the complete closing binder for the Archer acquisition.
- **Topic 39b:** Natera seeks testimony about R&D efforts undertaken by "researchers at Massachusetts General Hospital [("MGH")]." Ex. 19. MGH is not a party in this matter and Defendants do not have a witness to testify about work undertaken by a third party. Natera has served deposition notices upon the inventors of Archer's AMP technology, who are employed at MGH, and will be deposing them shortly. D.I. 256–57. Natera references a separate litigation to suggest that Archer has corporate understanding of MGH. That case is readily distinguishable, however, because MGH was a party to the litigation; not so here. Moreover, the cite Natera relies upon does not show a corporate understanding, but simply asserts that Archer obtained a license to the technology from MGH.
- **Topic 50:** Natera Topic 50 is a vague and confusing topic that appears to seek nothing but contentions relating to Defendants' unclean hands defense, which is not permitted. Ex. 19. To the extent the topic is deemed to request factual information, that information is solely about the timing of when Natera filed its patents, which is a matter of public record and not something that calls for 30(b)(6) testimony.

Respectfully submitted,

/s/ Michael J. Farnan

Michael J. Farnan

cc: Counsel of Record (Via E-Mail)